

German BVL hosts conference regarding national registration of plant protection products

Because of the rapid changes that occur in the regulatory world of plant protection products (PPPs), continual updates are necessary. The impact on national registrations of PPPs is reflected in new conclusions and procedures. The German Federal Office for Consumer Protection and Food Safety (BVL) regularly updates applicants on the developments on European and international levels, and how the new requirements are implemented on the national level in Germany. The latest information pertaining to the registration of PPPs was held on 29 April 2009 in Braunschweig, and was open to all applicants. The following summarizes the topics covered.

National registration of plant protection products

Dr. H. Bruno (BVL)
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Status of registrations: Pre-evaluation

In 2008, 86 main and supplementary applications were submitted to the BVL, and 19 in 2009 (through 24 April 2009). Currently 54 applications are in the completeness check phase and 29 in the plausibility check phase.

Suggestions to improve applications include:

- If reference to a dossier from other applicants is made (e.g. via a Letter of Access (LOA)), a reference list for the parts referred to should be submitted either by the applicant or by the company issuing the LOA directly to the BVL to avoid losing time because the BVL has to look for the respective studies.
- If submitted electronically, the scanned documents must be of sufficient quality, i.e.

should not contain watermarks across the pages covering important text, and should not contain shading of headers or text to highlight points.

- Material safety data sheets should not be combined in one file, but rather be provided as individual documents. They must be submitted under Document H and Document KIIA 3.7.

Delays occur in the mutual recognition procedure if the BVL has to secure evaluation reports from other Member States. If the BVL is to consider the evaluation report from another Member State, the respective documents have to be provided before mutual recognition can be granted. The BVL homepage contains detailed information on the mutual recognition procedure as well as which documents are to be provided.

If an electronic application makes reference to a second electronic application, it will be delayed until this second application has finished its pre-evaluation.

In Germany, the data protection system has been changed from the current practise to grant 10 years after national registration and again 10 years after Annex I listing, to only one time 10 years after national registration, as prescribed in 91/414.

Status of registrations: Main-evaluation

As of 27 April 2009, 342 applications are under evaluation at the BVL. Of these, 28 were blocked after the pre-evaluation and 44 after the main evaluation. Fifty-four applications have been delayed during the evaluation phase and 18 during the risk management phase. The BVL expects to issue approximately 60 registrations this year.

With the revision of 91/414, more work is expected to result since the current standard registration period of 10 years will no longer be

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routinely granted, but rather might be shortened to reflect the concern on certain substances. The BVL is currently researching possibilities to accommodate such changes in their national review process.

Classification and labelling according to CLP

Regulation (EC) No. 1272/2008 entered into force on 20 January 2009. The main changes will be:

- new pictograms
- new R- and S-phrases
- new signal words
- changes in some concentration values
- additional hazard classes
- applies to more mixtures.

The transition periods are:

For substances: 1 December 2010

For mixtures: 1 June 2015

The new classifications can already be included on the labels. It is important to note that the label can reflect only one classification, either according to the old or the new system. Both classifications can be given in the material safety data sheet.

Starting 1 December 2010 material safety data sheets for formulants in the application for plant protection products must reflect the classification according to the new system.

Starting 1 May 2009 the German Federal Institute for Risk Assessment (BfR) will provide the classification of active substances according to the new system in the official registration certificate.

Implementation of the EU Regulation for the substitution of Directive 91/414/EEC

Dr. H.G. Nolting

The revision of 91/414 will be issued as a regulation to avoid possible problems in implementing the document into national law.

The evaluation of a national application for a plant protection product can start in the Rapporteur Member State (RMS) as soon as the Draft Assessment Report (DAR) is made available.

The new regulation must be regarded in connection with the framework for the Community action to achieve a sustainable use of pesticides, which is less complicated and further developed at this time.

For Germany, it is important to note that the substitution principle will be applied on the level of plant protection products or, in particular, on the level of individual applications. Thus, only individual applications would be replaced if the substitution principle applies.

The number of active substances in registered plant production products in Germany has been nearly constant since 1993 at 200-250 actives. The number of registered application areas has been increased.

The German authorities will have to revise their procedure for evaluating plant protection products to adhere to the 120-day period prescribed in the regulation for zonal approvals and mutual recognition.

Practical experiences of mutual recognition according to § 15b PflSchG in Germany

Dr. D. Gottschild

To date Germany has approved the following mutual recognitions:

- 1 from Finland
- 2 from UK
- 2 from The Netherlands
- 1 from Denmark
- 1 from Italy

In the cases of mutual recognitions from Finland and Italy, where the climatic conditions are different from Germany, the recognitions were granted for indoor or stored product protection.

Currently, 27 mutual recognition applications are in the main evaluation phase (originating from UK, AT, NL, IT and DK) and 18 in the pre-evaluation phase (originating from UK, FR, IRL, NL, DK, IT, BE and SLO).

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The BVL has published a guideline for mutual recognition (last version June 2008) as well as a checklist of the necessary documents in German and English. These can be found in Internet on the BVL website.

To be able to apply for a mutual recognition registration, the original registration must have been issued according to Article 4 of Directive 91/414/EEC. A mutual recognition cannot be granted on an existing mutual recognition. The BVL experiences problems in issuing registrations if the original application was granted based on data of a previous applicant, since the data are normally not explicitly stated on the registration report. To speed up the application, the applicant can also select only specific intended uses compared to the original registration (e.g. outdoor used in countries not comparable to Germany). It is not possible to extend an existing German registration with a mutual recognition. It is, however, possible to use similar product names for both, the German registration and the registration based on the mutual recognition. Distribution extensions can be granted based on registrations granted on the basis of mutual recognition.

New developments (e.g. the issue of co-formulants containing tallowamine, etc) will also be addressed in a mutual recognition evaluation by the German authorities. Germany will then ask for the same data that is required for normal German applications. Mutual recognition applications would then also be blocked if needed.

The BVL asks applicants not to change the applications for the products (e.g. number of applications or amount of a.s. applied) in advance! This will be done by the German authorities during the registration process.

A new development in the revision of Directive 91/414/EEC is the possibility for associations and official institutes to apply for mutual recognition for products they do not own. This will not be possible for companies: they can only apply for mutual recognition of their own products.

Currently, the evaluation time for a mutual recognition in Germany is approximately as long as for a regular application. In the EU regulation for the substitution of Directive 91/414/EEC, the period for granting an approval by mutual recognition is limited to 120 days.

Specials rules will be developed for tank mixtures, home and garden uses, and minor uses (off-label uses).

Miscellaneous information according the registration procedure

Dr. A. Wilkening

The evaluation reports by the authorities (BVL, Julius Kühn-Institut (JKI), BfR and the German Federal Environmental Agency (UBA)) are attachments to the registration report of the BVL. Beginning this May, the evaluation report without attachments can be found on the BVL website (starting with the March expert meeting (SVA)). The individual authorities are responsible for putting their evaluation reports on the Internet. Reports on products which failed to receive approval will not be published. The current access to files by e-mail will be terminated 30 June 2009. Access will then be possible:

- via the BVL portal (electronic applications only)
- at the BVL in Braunschweig
- by postal service (if visiting the BVL is not feasible)

The following applies to substances voluntarily withdrawn from the EU procedure and re-submitted according to 33/2008:

- Extension of approvals until 31 December 2010 is possible upon application.
- Extension of uses and paragraph 18a (off-label uses) can be requested.
- New and re-registrations according to paragraph 15 are not possible.

- Ongoing paragraph 15 applications will be stopped. Those in the pre-evaluation stage will not enter the main evaluation phase until the additional report (addendum to DAR evaluating the re-submission) is available. Those already in the main evaluation will be stopped and blocked with a second interim report. The evaluation will continue when the additional report becomes available. This is also the time to provide additional data to the BVL which was generated for the EU process.

Information about the EU evaluation of active substances: completion of first existing active substance program 2009 and future activities (re-submission, renewals, new active substances, etc.)

Dr. H. Kula

With respect to the evaluation program for existing active substances, 8 active substances have not yet been decided to date. Seven were introduced at the last standing committee; however, no consensus could be reached. The remaining active substance is to be introduced at the next standing committee meeting.

The BVL has also assessed the work to be done by the EU (EU bodies and EU Member States) until the end of 2010:

- New a.s.: more than 53 DARs
- Green track a.s. (1095/2007): 68 a.s.
- Re-submissions (33/2008):
 - Voluntarily withdrawn: 59 a.s.
 - Dark red: 7 a.s.
 - Non-inclusions onto Annex I after peer review: 5 a.s.
- Confirmatory data evaluation: 26 a.s.

This requires the evaluation of a total of 227 a.s. in 2009 and 2010. The number of evaluations is higher than it has been during the entire review

program to date for the same time period. The pesticide steering committee, which was established at the end of 2008, is set to manage this task.

First experience with the implementation of the Directive (EC) No. 396/2005

D. K. Hohgardt

The BVL currently estimates a delay of approximately 3 months in the evaluation for active substances as identified under Article 12 paragraph 2. For active substances as identified under Article 12 paragraph 1, Germany has sent out all their requests for dossiers to applicants and Member States, but concedes that the response from the Member States is slow. Under the same work routine, Germany has so far only received a request from NL. The BVL currently estimates a significant delay for the evaluation of substances under Article 12 paragraph 1

In principle, approvals can be granted even for substances for which no MRL is set if the residues are below 0.01 ppm.

The listing procedure for additives

Dr. A. Makulla

All necessary information to apply for a listing of an adjuvant is published on the BVL homepage. "The Plant Protection Act (Art. 31c No 1) defines adjuvants (additives) as substances which are intended to be added to plant protection products to change their properties or effects, e.g. to improve the wettability or adhesion of plant protection products or to reduce foaming" (source: BVL homepage). Water and fertilizers are excluded from this definition.

Once the BVL has confirmed completeness, 4 months are planned for the evaluation: 10 weeks are planned for BfR, UBA and JKI. Costs for the standard procedure are €570. If extended evaluations are necessary, costs may range from €7,470 to 29,200.

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Distribution extensions are possible. Listing of adjuvants/additives is not limited by time.

No risk management, i.e. buffer zones to protect bodies of water, is foreseen in the listing procedure: either the listing is granted or it is not.

A European harmonisation of the listing procedures is intended. Until then, national procedures apply.

Increase in number of electronic applications

Dr. H. Bruno

The advantages to present electronic applications are:

- Quick application via the BVL portal
- Safer exchange of sensitive data via the BVL portal
- Better management of the applications due to electronic handling only
- More transparency
- No paper copies of the dossier required (only legally binding documents, such as a

Letter of Access, are to be submitted in paper form)

- Application forms are filled in correctly by using drop down code lists.

This has led to about a 35% faster evaluation of electronic applications as compared to conventional paper applications.

To further increase the number of electronic applications, it is also possible to refer to previous applications which were conventional applications and submitted after 1 July 2007 (the BVL has scanned all of these applications). If electronic applications make reference to a paper dossier of other applicants (e.g. via a Letter of Access), a reference list of the parts referred to should be submitted either by the applicant or by the company issuing the letter directly to the BVL to avoid time loss due to the BVL having to look for the respective studies. Reference to this additional reference list should be made in the application under '8. Bemerkungen' and they should be included into the CADDY under "Additional documents/Reference lists". Also, the BVL is currently investigating the possibility of a fee reduction for electronic applications.

If you would like to know what these new provisions mean for the approval of your active substances, please contact Dr. Albrecht Heidemann at albrecht.heidemann@scc-gmbh.de.

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